



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852 by contacting Dr. Benjamin Hurley at 240-669-5092 or benjamin.hurley@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Engineered Cell-Penetrating Monoclonal Antibody for Universal Influenza Immunotherapy.

Description of Technology:

Influenza remains a burden on public health, as current treatments of viral infections remain ineffective due to frequent virus mutations. Many current influenza treatments rely on targeting surface viral glycoproteins. Unfortunately, these glycoproteins are primary targets of the immune system, which results in increased selection pressure and mutational rate, leading to the well-known seasonal variation of influenza virus. In

contrast, the nucleocapsid viral protein (NP), located in the interior of the virus, is more conserved and an ideal antibody target; however, NP is inaccessible to extracellular antibodies produced in response to infection. To circumvent the challenge of targeting NP, scientists at NIAID have developed an antibody genetically fused with a cell penetrating peptide (CPP-mAb) that targets NP within infected cells to effectively inhibit viral replication. By targeting NP rather than the surface glycoproteins, this CPP-mAb can treat more influenza variants, potentially across flu seasons, and is an improvement upon current influenza treatments.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Clinical Treatment: CPP-mAbs against influenza NP may be a reliable and effective method to treat patients infected with varying subtypes of influenza, by targeting a functionally conserved protein.
- CPP-mAbs could be a viable alternative to the treatment of influenza when other treatments are ineffective, potentially lowering the mortality and morbidity rates in populations susceptible to influenza infection.

Competitive Advantages:

- Current vaccines remain effective for a short time period, due to the ever-changing nature of the viral surface glycoproteins. CPP-mAbs could remain effective for a longer time period by targeting the interior NP of influenza, which is more conserved across influenza subtypes.
- Other attempts to produce vaccines against conserved portions of the surface viral glycoproteins have failed to produce a robust and reliable vaccine. CPP-mAbs could

be a more reliable therapeutic agent compared to alternatives, potentially effective across flu seasons.

- *In vivo* efficacy: CPP-mAbs against NP increase survivorship in mice infected with mouse Influenza A virus, demonstrating therapeutic protection.

Development Stage:

- Pre-Clinical

Inventors: Jonathon Yewdell, MD, PhD and Ivan Kosik, PhD, both from NIAID

Publications: Publication pending

Intellectual Property: HHS Reference No. E-193-2021; US Provisional Application No. 63/365,841, filed on June 3rd, 2022.

Licensing Contact: To license this technology, please contact Benjamin Hurley at 240-669-5092 or benjamin.hurley@nih.gov, and reference E-193-2021.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this invention. For collaboration opportunities, please contact Benjamin Hurley; 240-669-5092, benjamin.hurley@nih.gov.

Dated: April 19, 2023.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.